

*December 10, 1999*

*Page 4*

## **REMARKS**

Applicants would like to thank Examiner Weatherspoon for the courtesy of a telephone interview, at which the reasons behind Examiner Weatherspoon's refusal to consider claims 41-42, 45 and 48 were clarified. Applicants agreed to supply reasons why these claims should be examined in their response to the outstanding Office Action. Further, the basis for the rejection under 35 U.S.C. 112, second paragraph, was clarified to help Applicants in preparing a response to the Office Action.

### **The Amendments**

The specification is amended to perfect the claim to priority from the provisional application as requested in the present Office Action.

Claim 30 is amended to clarify the claim by expressly incorporating a requirement for stringent hybridization between the claimed nucleic acid and one or more members of the Markush group of specifically recited nucleic acids. Conditions for stringent hybridization are expressly taught in the specification (see, e.g., page 9, lines 22-31). Claims 40 and 46 are amended herein to clarify the antecedent basis of various terms in the claim. Claim 41 is amended to clarify the type of compound claimed, as requested by the Examiner in the telephone interview. Claim 42 is amended to clarify the type of assay (assay for specific nucleic acid based on hybridization) as taught in the specification, see, e.g., page 30, text following line 19, and page 44, lines 6-16.

Claims 43 and 44 are amended to clarify the type of composition claimed therein. Applicants submit that the present claim amendments clarify claims to subject matter fully

*December 10, 1999*

*Page 5*

described in the specification. These amendments being fully supported in the application as-filed, Applicants respectfully request that the amendments be entered in the application.

**Unexamined claims**

Claims 41-42, 45 and 48 have not been examined on the grounds that they are drawn to unelected inventions. Applicants respectfully point out that they have elected Group I, drawn to nucleic acids encoding TbpA protein (Amendment filed March 2, 1998).

Claims 41 and 45 are drawn to nucleic acids complimentary to the nucleic acid encoding TbpA protein, which sequences are included within the elected Group, based on the definition of nucleic acids in the specification ("The term 'nucleic acid' is intended to include DNA and RNA and can be either double stranded or single stranded." Page 8, lines 32-33. "The invention also includes nucleic acids sequence complementary to the [claimed nucleic acid]." Page 9, line 3.) Furthermore, Applicants point out that the elected nucleic acids include both single-stranded and double-stranded nucleic acid, and double-stranded nucleic acid inherently comprises both sense and antisense sequences. Therefore, Applicants respectfully submit that claims 41 and 45 are drawn to nucleic acids within the elected Group.

Claims 42 and 48 are drawn to assays to detect the claimed nucleic acid and kit containing the nucleic acid. Applicants respectfully submit that these claims are intimately associated with the claimed nucleic acid as elected, and, to the extent claims to the elected nucleic acid are patentable, assays as recited in claim 42, and kits for use in such assays as recited in claim 48, are equally patentable, so no additional search is required. Applicants respectfully request that claims 41-42, 45 and 48, as amended herein, be included within the examined claims.

*December 10, 1999*

*Page 6*

**Information Disclosure Statement**

Applicants thank the Examiner for pointing out that the list of references included in the specification itself have not necessarily be considered by the Examiner. Applicants note that numerous documents are of record in the present application, as indicated in Forms PTO 892 accompanying Papers No. 6 and 15, and Forms PTO 1449 filed June 10, 1997 and April 5, 1999.

**Rejection Under 35 U.S.C. §112, second paragraph**

Claims 30-40, 43-44, 46-47, and 49-51 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully submit that, subsequent to entry of the present amendments, the claims are clear and unambiguous.

Claim 30 is amended herein to delete the term "80 percent identity". Claim 30 as amended is limited to nucleic acids which hybridize with the recited sequences under stringent conditions, stringent conditions being fully defined in the specification, *inter alia*, page 9, lines 22-31. Thus, claim 30 as amended provides a clear standard for ascertaining the metes and bounds of the claimed nucleic acids.

Claim 40 as amended is drawn to a heterologous nucleic acid molecule comprising the recited nucleic acid sequence. It is recognized in the art that a heterologous nucleic acid molecule comprises nucleic acid sequences from two or more distinct species or strains. Claim 40 as amended is consistent with this definition. Claims 43 and 44 are amended to eliminate any suggestion that a nucleic acid molecule encodes another nucleic acid molecule. Claim 44 and 46 are amended to clarify the antecedent basis for the terms identified in the Office Action. Applicants respectfully submit that claims 30-40, 43-44, 46-47 and 49-51, as amended

*December 10, 1999*

*Page 7*

herein, particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Therefore, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

**Rejection Under 35 U.S.C. §102(b)**

Claims 30-31, 33, 43-44, and 46-47 stand rejected under 35 U.S.C. §102(b) as anticipated by Murphy, et al. (1993). This rejection is respectfully traversed.

Applicants respectfully point out that the pending claims are drawn to isolated nucleic acid, which is defined in the specification on page 8, lines 30-32 as, "free of sequences which naturally flank the nucleic acid [] from which the nucleic acid is derived." Murphy discloses a preparation of total genomic DNA from a particular organism, and the DNA fragments disclosed by Murphy will inherently contain the flanking sequences found in the organism whose total DNA is prepared. This is not isolated nucleic acid as defined in the specification, page 8, lines 30-32, and therefore Murphy, et al. (1993) does not disclose or suggest the isolated nucleic acid as claimed herein.

Furthermore, Murphy provides no guidance on separating fragments of DNA which will hybridized under stringent conditions with the sequences recited in the sequence listing. Thus, Murphy does not enable the public to obtain the nucleic acid of amended claim 30 or claims dependent thereon. Chester v. Miller, 906 F.2d 1574, 1577 n.2, 15 USPQ2d 1333, 1336 n.2 (Fed. Cir. 1990) ("To be prior art under section 102(b) the reference must put the anticipating subject matter at issue into the possession of the public through an enabling disclosure.").

*December 10, 1999*

*Page 8*

Applicants respectfully request that the rejection of claims 30-31, 33, 43-44, and 46-47 under 35 U.S.C. §102(b) be withdrawn.

Applicants note that the 1996 and 1997 references submitted with the prior response to make of record the types of conditions which must be used to extract full length/intact chromosomal DNA are drawn to inherent characteristics of a biologic system i.e., chromosomal DNA in its native configuration, and the inherent characteristics of such a system did not change between the period prior to the effective filing date until after the effective filing date.

**Rejection Under 35 U.S.C. §103(a)**

Claims 30-31, 33, 36-39, 43-44, 46-47, and 49-51 stand rejected under 35 U.S.C. §103(a) as unpatentable over Murphy, et al., described above, in view of Schryvers, et al., (1992) and further in view of Loosmore, et al. Applicants note that amended claim 30 does recite "stringent hybridization conditions" and, as set forth above, Murphy does not provide an isolated nucleic acid as claimed. Nor does Murphy provide any guidance by which the skilled worker might reasonable expect to obtain the claimed nucleic acid fragments from the total genomic DNA provided by Murphy. Therefore, the claims as amended herein are not obvious over Murphy.

Furthermore, the Schryvers, et al. and Loosmore, et al. references do not supply the deficiencies of Murphy. In particular, neither Schryvers nor Loosmore provide any reasonable expectation of success in isolating the claimed nucleic acid. Therefore, claims 30-31, 33, 36-39, 43-44, 46-47, and 49-51 are not obvious over cited references for the reasons provided

*December 10, 1999*

*Page 9*

herein and in the previous response. Applicants respectfully request that the rejection of the claims as amended herein under 35 U.S.C. §103(a) be withdrawn.

Applicants note that claims 32, 34, 35 and 40 have not been rejected under 35 U.S.C. §§102 or 103, and therefore have been indicated to be free of the prior art.

**Conclusion**

Applicants respectfully submit that all of the pending claims, as amended herein, are now in condition for allowance, and respectfully request an indication of same. If the Examiner believes that prosecution may be furthered by discussing the application, in person or by telephone, with Applicants' representatives, we would welcome the opportunity to do so.

Respectfully submitted,

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